

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61B 17/12		A1	(11) International Publication Number: WO 98/29041 (43) International Publication Date: 9 July 1998 (09.07.98)
(21) International Application Number: PCT/US97/24116		(81) Designated States: BR, CA, CN, IL, JP, MX, RU, European patent (AT, BE, CH, DR, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 31 December 1997 (31.12.97)		Published <i>With international search report.</i>	
(30) Priority Data: 08/778,277 2 January 1997 (02.01.97) US 08/933,456 18 September 1997 (18.09.97) US			
(71) Applicant: MYOCOR, INC. [US/US]; Suite 200W-B, 1380 Energy Lane, St. Paul, MN 55108 (US).			
(72) Inventors: SCHWEICH, Cyril, Jr.; 1685 Hillcrest Avenue, St. Paul, MN 55116 (US). MORTIER, Todd, J.; 3022 DuPont Avenue South, Minneapolis, MN 55408 (US).			
(74) Agents: SEAGER, Glenn, M. et al.; Nawrocki, Rooney & Sivertson, P.A., Suite 401, Broadway Place East, 3433 Broadway Street Northeast, Minneapolis, MN 55413-3009 (US).			
(54) Title: HEART WALL TENSION REDUCTION APPARATUS AND METHOD			
(57) Abstract			
<p>This invention is an apparatus for treatment of a failing heart by reducing the wall tension therein. In one embodiment, the apparatus includes a tension member (18) for drawing at least two walls of a heart chamber toward each other. Methods for placing the apparatus on the heart are also provided.</p>			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AI	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BI	Betim	IR	Iceland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NR	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LJ	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

HEART WALL TENSION REDUCTION APPARATUS AND METHODCross Reference to Related Application

This application is a continuation-in-part of U.S. Application Serial No. 08/778,277, filed January 2, 1997, 5 entitled "HEART WALL TENSION REDUCTION APPARATUS".

Field of the Invention

The present invention pertains to the field of apparatus for treatment of a failing heart. In 10 particular, the apparatus of the present invention is directed toward reducing the wall stress in the failing heart.

Background of the Invention

15 The syndrome of heart failure is a common course for the progression of many forms of heart disease. Heart failure may be considered to be the condition in which an abnormality of cardiac function is responsible for the inability of the heart to pump blood at a rate 20 commensurate with the requirements of the metabolizing tissues, or can do so only at an abnormally elevated filling pressure. There are many specific disease processes that can lead to heart failure with a resulting difference in pathophysiology of the failing heart, such 25 as the dilatation of the left ventricular chamber. Etiologies that can lead to this form of failure include

idiopathic cardiomyopathy, viral cardiomyopathy, and ischemic cardiomyopathy.

The process of ventricular dilatation is generally the result of chronic volume overload or specific damage 5 to the myocardium. In a normal heart that is exposed to long term increased cardiac output requirements, for example, that of an athlete, there is an adaptive process of slight ventricular dilation and muscle myocyte hypertrophy. In this way, the heart fully compensates 10 for the increased cardiac output requirements. With damage to the myocardium or chronic volume overload, however, there are increased requirements put on the contracting myocardium to such a level that this compensated state is never achieved and the heart 15 continues to dilate.

The basic problem with a large dilated left ventricle is that there is a significant increase in wall tension and/or stress both during diastolic filling and during systolic contraction. In a normal heart, the 20 adaptation of muscle hypertrophy (thickening) and ventricular dilatation maintain a fairly constant wall tension for systolic contraction. However, in a failing heart, the ongoing dilatation is greater than the hypertrophy and the result is a rising wall tension 25 requirement for systolic contraction. This is felt to be an ongoing insult to the muscle myocyte resulting in

further muscle damage. The increase in wall stress is also true for diastolic filling. Additionally, because of the lack of cardiac output, there is generally a rise in ventricular filling pressure from several physiologic mechanisms. Moreover, in diastole there is both a diameter increase and a pressure increase over normal, both contributing to higher wall stress levels. The increase in diastolic wall stress is felt to be the primary contributor to ongoing dilatation of the chamber.

Prior art treatments for heart failure fall into three generally categories. The first being pharmacological, for example, diuretics. The second being assist systems, for example, pumps. Finally, surgical treatments have been experimented with, which are described in more detail below.

With respect to pharmacological treatments, diuretics have been used to reduce the workload of the heart by reducing blood volume and preload. Clinically, preload is defined in several ways including left ventricular end diastolic pressure (LVEDP), or left ventricular end diastolic volume (LVEDV). Physiologically, the preferred definition is the length of stretch of the sarcomere at end diastole. Diuretics reduce extra cellular fluid which builds in congestive heart failure patients increasing preload conditions. Nitrates, arteriolar vasodilators, angiotensin converting

enzyme inhibitors have been used to treat heart failure through the reduction of cardiac workload through the reduction of afterload. Afterload may be defined as the tension or stress required in the wall of the ventricle 5 during ejection. Inotropes like digoxin are cardiac glycosides and function to increase cardiac output by increasing the force and speed of cardiac muscle contraction. These drug therapies offer some beneficial effects but do not stop the progression of the disease.

10 Assist devices include mechanical pumps and electrical stimulators. Mechanical pumps reduce the load on the heart by performing all or part of the pumping function normally done by the heart. Currently, mechanical pumps are used to sustain the patient while a 15 donor heart for transplantation becomes available for the patient. Electrical stimulation such as bi-ventricular pacing have been investigated for the treatment of patients with dilated cardiomyopathy.

There are at least three surgical procedures for 20 treatment of heart failure: 1) heart transplant; 2) dynamic cardiomyoplasty; and 3) the Batista partial left ventriculectomy. Heart transplantation has serious limitations including restricted availability of organs and adverse effects of immunosuppressive therapies 25 required following heart transplantation.

Cardiomyoplasty includes wrapping the heart with skeletal

muscle and electrically stimulating the muscle to contract synchronously with the heart in order to help the pumping function of the heart. The Batista partial left ventriculectomy includes surgically remodeling the 5 left ventricle by removing a segment of the muscular wall. This procedure reduces the diameter of the dilated heart, which in turn reduces the loading of the heart. However, this extremely invasive procedure reduces muscle mass of the heart.

10

Summary of the Invention

The present invention pertains to a non-pharmacological, passive apparatus and method for the treatment of a failing heart. The device is configured 15 to reduce the tension in the heart wall. It is believed to reverse, stop or slow the disease process of a failing heart as it reduces the energy consumption of the failing heart, decreases isovolumetric contraction, increases sarcomere shortening during contraction and increases 20 isotonic shortening which in turn increases stroke volume. The device reduces wall tension during diastole and systole.

In one embodiment, the apparatus includes a tension member for drawing at least two walls of the heart 25 chamber toward each other to reduce the radius or area of the heart chamber in at least one cross sectional plane.

The tension member has anchoring members disposed at opposite ends for engagement with the heart or chamber wall.

In another embodiment, the apparatus includes a 5 compression member for drawing at least two walls of a heart chamber toward each other. In one embodiment, the compression member includes a balloon. In another embodiment of the apparatus, a frame is provided for supporting the compression member.

10 Yet another embodiment of the invention includes a clamp having two ends biased toward one another for drawing at least two walls of a heart chamber toward each other. The clamp includes at least two ends having atraumatic anchoring member disposed thereon for 15 engagement with the heart or chamber wall.

In yet another embodiment, a heart wall tension reduction apparatus is provided which includes a first tension member having two oppositely disposed ends and first and second elongate anchor members. A second 20 tension member can be provided. One of the elongate anchors may be substituted for by two smaller anchors.

In an alternate embodiment of the heart wall tension reduction apparatus, an elongate compression member can be provided. First and second elongate lever members 25 preferably extend from opposite ends of the compression

member. A tension member extends between the first and second lever members.

The compression member of the above embodiment can be disposed exterior to, or internally of the heart. The 5 tension member extends through the chamber or chambers to bias the lever members toward the heart.

In yet another embodiment of a heart wall tension reduction apparatus in accordance with the present invention, a rigid elongate frame member is provided. 10 The frame member can extend through one or more chambers of the heart. One or more cantilever members can be disposed at opposite ends of the frame member. Each cantilever member includes at least one atraumatic pad disposed thereon. The atraumatic pads disposed at 15 opposite ends of the frame member can be biased toward each other to compress the heart chamber.

One method of placing a heart wall tension apparatus or splint on a human heart includes the step of extending a hollow needle through at least one chamber of the heart 20 such that each end of the needle is external to the chamber. A flexible leader is connected to a first end of a tension member. A second end of the tension member is connected to an atraumatic pad. The leader is advanced through the needle from one end of the needle to 25 the other. The leader is further advanced until the second end of the tension member is proximate the heart

and the first end of the tension member is external to the heart. A secondatraumatic pad is connected to the first end of the tension member such that the first and second atraumatic pads engage the heart.

5 An alternate method of placing the heart wall tension reduction apparatus on the heart includes the step of extending a guide member through at least one chamber of the heart such that each end of the guide member is external to the chamber. A tension member for
10 use in this method has at least one lumen extending through at least a portion of the member. The guide member is placed in the lumen. The tension member is advanced over the guide member such that a first end of the tension member is disposed to one side of and
15 external to the heart and a second end of the tension member is disposed to an opposite side of and external to the heart. A first atraumatic pad is connected to one end of the tension member and a second atraumatic pad is connected to the opposite end of the tension member.

20 Yet another method of placing a heart wall tension apparatus on a heart includes the step of extending a needle having a flexible tension member releasably connected thereto through at least one chamber of the heart such that opposite ends of the tension member are
25 external to the chamber and exposed on opposite sides of the chamber. The needle is removed from the tension

member. Then first and second atraumatic pads are connected to the tension member at opposite ends of the tension member.

5

Brief Description of the Drawings

Figure 1 is a transverse cross-section of the left and right ventricles of a human heart showing the placement of a splint in accordance with the present invention;

10

Figure 2 is a transverse cross-section of the left and right ventricles of a human heart showing the placement of a balloon device in accordance with the present invention;

15

Figure 3 is a transverse cross-section of the left and right ventricles of a human heart showing the placement of an external compression frame structure in accordance with the present invention;

20

Figure 4 is a transverse cross-section of the left and right ventricles of a human heart showing a clamp in accordance with the present invention;

Figure 5 is a transverse cross-section of the left and right ventricles of a human heart showing a three tension member version of the splint of Figure 1;

25

Figure 6 is a transverse cross-section of the left and right ventricles of a human heart showing a four tension member version of the splint shown in Figure 1;

Figure 7 is a vertical cross-sectional view of the left ventricle of a human heart showing an alternate version of the splint in accordance with the present invention;

5 Figure 8 is an end of the splint shown in Figure 7;

Figure 9 is a vertical cross-sectional view of a chamber of a human heart showing another alternative embodiment of the splint in accordance with the present invention;

10 Figure 10 is a vertical cross-section of a chamber of a human heart showing another alternative configuration of splints in accordance with the present invention;

Figure 11 is a vertical cross-sectional view of a 15 chamber of a human heart showing another embodiment of a splint in accordance with the present invention;

Figure 12 is a vertical cross-sectional view of a chamber of a human heart showing another embodiment of the splint in accordance with the present invention;

20 Figure 13 is a vertical cross-sectional view of a chamber of a human heart showing a compression member version of the splint in accordance with the present invention;

Figure 14 is a vertical cross-sectional view of a 25 chamber of a human heart showing another version of the splint shown in Figure 13;

Figure 15 is a vertical cross-sectional view of a chamber of a human heart showing a frame member version of the splint in accordance with the present invention;

Figure 16 is an end view of the splint of Figure 15;

5 Figure 17 is a vertical cross-section of the left ventricle and atrium, the left ventricle having scar tissue;

Figure 18 is a vertical cross-section of the heart of Figure 7 showing the splint of Figure 1 drawing the 10 scar tissue toward the opposite wall of the left ventricle;

Figure 19 is a vertical cross-section of the left ventricle and atrium of a human heart showing a version of the splint of Figure 1 having an elongate anchor bar;

15 Figure 20 is a side view of an undeployed hinged anchor member;

Figure 21 is a side view of a deployed hinged anchor member of Figure 10;

20 Figure 22 is a cross-sectional view of an captured ball anchor member;

Figure 23 is a perspective view of a cross bar anchor member;

Figure 24 is a vertical cross-sectional view of a chamber of a human heart showing a needle used for 25 placement of splint in accordance with the present invention;

Figure 25 is a view of the heart and needle of Figure 24 showing a tension member being placed in the heart;

Figure 26 is a view of the heart shown in Figure 24 5 wherein oppositely disposed anchor pads are being joined by a tension member;

Figure 27 is a view of the heart of Figure 24, wherein two oppositely disposed anchor pads have been joined by two tension members;

10 Figure 28 is a view of a tension member having a lumen extending therethrough;

Figure 29 is a view of a tension member having lumens extending therethrough;

15 Figure 30 is a vertical cross-sectional view of a chamber of the heart and two pads, and a needle extending therethrough;

Figure 31 is a vertical cross-sectional view of a chamber of the heart showing a guidewire extending therethrough;

20 Figure 32 is a view of the heart of Figure 31, and two pads, and a guidewire extending therethrough;

Figure 33 is a vertical cross-sectional view of a chamber of the heart showing a needle connected to a tension member being inserted into the chamber;

Figure 34 is a vertical cross-sectional view of a chamber of a heart showing two anchors connected by a tension member;

Figure 35 is a vertical cross-sectional view of a 5 chamber of the heart, showing a band surrounding the heart;

Figure 36 is a idealized cylindrical model of a left ventricle of a human heart;

Figure 37 is a splinted model of the left ventricle 10 of Figure 14;

Figure 38 is a transverse cross-sectional view of Figure 15 showing various modeling parameters;

Figure 39 is a transverse cross-section of the splinted left ventricle of Figure 15 showing a 15 hypothetical force distribution; and

Figure 40 is a second transverse cross-sectional view of the model left ventricle of Figure 15 showing a hypothetical force distribution.

20 Detailed Description of the Invention

Referring now to the drawings wherein like reference numerals refer to like elements throughout the several views, Figure 1 shows a transverse cross-section of a left ventricle 10 and a right ventricle 12 of a human heart 14. Extending through the left ventricle is a 25 splint 16 including a tension member 18 and oppositely

disposed anchors 20. Splint 16 as shown in Figure 1 has been positioned to draw opposite walls of left ventricle 10 toward each other to reduce the "radius" of the left ventricular cross-section or the cross-sectional area 5 thereof to reduce left ventricular wall stresses. It should be understood that although the splint 16 and the alternative devices disclosed herein are described in relation to the left ventricle of a human heart, these devices could also be used to reduce the radius or cross- 10 sectional area of the other chambers of a human heart in transverse or vertical directions, or at an angle between the transverse and vertical.

Figure 2 discloses an alternate embodiment of the present invention, wherein a balloon 200 is deployed 15 adjacent the left ventricle. The size and degree of inflation of the balloon can be varied to reduce the radius or cross-sectional area of left ventricle 10 of heart 14.

Figure 3 shows yet another alternative embodiment of 20 the present invention deployed with respect to left ventricle 10 of human heart 14. Here a compression frame structure 300 is engaged with heart 14 at atraumatic anchor pads 310. A compression member 312 having an atraumatic surface 314 presses against a wall of left 25 ventricle 10 to reduce the radius or cross-sectional area thereof.

Figure 4 is a transverse cross-sectional view of human heart 14 showing yet another embodiment of the present invention. In this case a clamp 400 having atraumatic anchor pads 410 biased toward each other is 5 shown disposed on a wall of left ventricle 10. Here the radius or cross-sectional area of left ventricle 10 is reduced by clamping off the portion of the wall between pads 410. Pads 410 can be biased toward each other and/or can be held together by a locking device.

10 Each of the various embodiments of the present invention disclosed in Figures 1-4 can be made from materials which can remain implanted in the human body indefinitely. Such biocompatible materials are well-known to those skilled in the art of clinical medical 15 devices.

Figure 5 shows an alternate embodiment of the splint of Figure 1 referred to in Figure 5 by the numeral 116. The embodiment 116 shown in Figure 5 includes three tension members 118 as opposed to a single tension member 20 18 as shown in Figure 1. Figure 6 shows yet another embodiment of the splint 216 having four tension members 218. It is anticipated that in some patients, the disease process of the failing heart may be so advanced 25 that three, four or more tension members may be desirable to reduce the heart wall stresses more substantially than

possible with a single tension member as shown in Figure 1.

Figure 7 is a partial vertical cross-section of human heart 14 showing left ventricle 10. In Figure 7, 5 another splint embodiment 316 is shown having a tension member 318 extending through left ventricle 10. On opposite ends of tension member 318 are disposed elongate anchors or pads 320. Figure 8 is an end view of tension member 318 showing elongate anchor 320.

10 Figure 9 shows another embodiment of a splint 416 disposed in a partial vertical cross-section of human heart 14. Splint 416 includes two elongate anchors or pads 420 similar to those shown in Figures 7 and 8. In Figure 9, however, two tension members 418 extend through 15 left ventricle 10 to interconnect anchors 420 on opposite sides of heart 14.

Figure 10 is a vertical cross section of heart 14 showing left ventricle 10. In this case, two splints 16 are disposed through left ventricle 10 and vertically 20 spaced from each other to resemble the configuration of Figure 9.

Figure 11 is a vertical cross sectional view of the left ventricle of heart 14. Two alternate embodiment splints 516 are shown extending through left ventricle 25 10. Each splint 516 includes two tension members 518 interconnecting two anchors or pads 520.

Figure 12 is yet another vertical cross sectional view of left ventricle 10 of heart 14. An alternate embodiment 616 of the splint is shown extending through left ventricle 10. Splint 616 includes an elongate 5 anchor pad 620 and two shorter anchors or pads 621. Splint 616 includes two tension members 618. Each tension member 618 extends between anchors 620 and respective anchors 621.

Figure 13 is a vertical cross sectional view of left 10 ventricle 10 of heart 14. A splint 50 is shown disposed on heart 14. Splint 50 includes a compression member 52 shown extending through left ventricle 10. Opposite ends of compression member 52 are disposed exterior to left ventricle 10. Lever members 54 extend from each end of 15 compression member 52 upwardly along the exterior surface of ventricle 10. A tension member 56 extends between lever members 54 to bias lever members 54 toward heart 14 to compress chamber 10. Compression member 52 should be substantially rigid, but lever members 54 and to some 20 degree compression member 52 should be flexible enough to allow tension member 56 to bias lever members 54 toward heart 14. Alternately, lever members 54 could be hinged to compression member 52 such that lever members 54 could pivot about the hinge when biased toward heart 14 by 25 tension member 56.

Figure 14 shows an alternate embodiment 156 of the splint shown in Figure 13. In this case lever members 154 are longer than members 54 as compression member 152 of splint 150 has been disposed to the exterior of left 5 ventricle 10.

Figure 15 is a vertical cross sectional view of left ventricle 10 of heart 14. An alternate embodiment 250 of the splint is shown on heart 14. A preferably relatively rigid frame member 256 extends through ventricle 10. 10 Disposed on opposite ends of frame 250 are cantilever member 254. Disposed on cantilever members 254 are atraumatic pads 258. Cantilever members 254 can be positioned along frame member 256 such that atraumatic pads 258 press against heart 14 to compress chamber 10. 15 Figure 16 is an end view of frame member 256 showing cantilever members 254 and pads 258.

It should be understood that each of the embodiments described above should be formed from suitable biocompatible materials known to those skilled in the 20 art. The tension members can be formed from flexible or relatively more rigid material. The compression members and frame member should be formed from generally rigid material which may flex under load, but generally hold its shape.

25 Figure 17 is a partial vertical cross-section of human heart 14 showing left ventricle 10 and left atrium

22. As shown in Figure 7, heart 14 includes a region of scar tissue 24 associated with an aneurysm or ischemia. As shown in Figure 7, the scar tissue 24 increases the radius or cross-sectional area of left ventricle 10 in 5 the region affected by the scar tissue. Such an increase in the radius or cross-sectional area of the left ventricle will result in greater wall stresses on the walls of the left ventricle.

Figure 18 is a vertical cross-sectional view of the 10 heart 14 as shown in Figure 7, wherein a splint 16 has been placed to draw the scar tissue 24 toward an opposite wall of left ventricle 10. As a consequence of placing splint 16, the radius or cross-sectional area of the left ventricle affected by the scar tissue 24 is reduced. The 15 reduction of this radius or cross-sectional area results in reduction in the wall stress in the left ventricular wall and thus improves heart pumping efficiency.

Figure 19 is a vertical cross-sectional view of left ventricle 10 and left atrium 22 of heart 14 in which a 20 splint 16 has been placed. As shown in Figure 9, splint 16 includes an alternative anchor 26. The anchor 26 is preferably an elongate member having a length as shown in Figure 9 substantially greater than its width (not shown). Anchor bar 26 might be used to reduce the radius 25 or cross-sectional area of the left ventricle in an instance where there is generalized enlargement of left

ventricle 10 such as in idiopathic dilated cardiomyopathy. In such an instance, bar anchor 26 can distribute forces more widely than anchor 20.

Figures 20 and 21 are side views of a hinged anchor 5 28 which could be substituted for anchors 20 in undeployed and deployed positions respectively. Anchor 28 as shown in Figure 20 includes two legs similar to bar anchor 26. Hinged anchor 28 could include additional legs and the length of those legs could be varied to 10 distribute the force over the surface of the heart wall.

In addition there could be webbing between each of the legs to give anchor 28 an umbrella-like appearance. Preferably the webbing would be disposed on the surface of the legs which would be in contact with the heart 15 wall.

Figure 22 is a cross-sectional view of a capture ball anchor 30. Capture ball anchor 30 can be used in place of anchor 20. Capture ball anchor 30 includes a disk portion 32 to distribute the force of the anchor on 20 the heart wall, and a recess 34 for receiving a ball 36 affixed to an end of tension member 18. Disk 32 and recess 34 include a side groove which allows tension member 38 to be passed from an outside edge of disk 32 into recess 34. Ball 36 can then be advanced into recess 25 34 by drawing tension member 18 through an opening 39 in recess 34 opposite disk 32.

Figure 23 is a perspective view of a cross bar anchor 40. The cross bar anchor 40 can be used in place of anchors 20. The anchor 40 preferably includes a disk or pad portion 42 having a cross bar 44 extending over an opening 46 in pad 42. Tension member 18 can be extended through opening 46 and tied to cross bar 44 as shown.

In use, the various embodiments of the present invention are placed in or adjacent the human heart to reduce the radius or cross-section area of at least one chamber of the heart. This is done to reduce wall stress or tension in the heart or chamber wall to slow, stop or reverse failure of the heart. In the case of the splint 16 shown in Figure 1, a canula can be used to pierce both walls of the heart and one end of the splint can be advanced through the canula from one side of the heart to the opposite side where an anchor can be affixed or deployed. Likewise, an anchor is affixed or deployed at the opposite end of splint 16.

Figure 24 is a vertical cross-sectional view of a chamber 10 of a heart 14. A needle 60 having a stylet inserted therethrough is inserted through chamber 10. Figure 25 shows needle 60 disposed in heart 40 as shown in Figure 24. In Figure 25, stylet 62 has been removed. A tension member 64 having a flexible leader 66 attached to one end of tension member 64, is threaded through needle 60 and an anchor 68.

As shown in Figure 25, tension member 64 includes a generally elongate cylindrical shaft 70 having two generally cylindrical ends 72. Ends 72 preferably have a greater diameter than shaft 70. Also shown in Figure 25 5 is a perspective view of anchor 68 showing an opening 73 extending through anchor 68. Opening 73 includes a first cylindrically shaped opening 74 extending entirely through anchor 68. The diameter of opening 74 is preferably slightly greater than the diameter of end 72 10 of tension member 64. A groove 76 having a width preferably slightly greater than that of shaft 70 of tension member 64 extends from opening 74 to a generally cylindrical opening 78. Generally cylindrical opening 78 has a diameter approximately equal to end 72. Unlike 15 opening 74, however, opening 78 includes a reduced base opening 80 which has a width approximately equal to that of groove 76. The width of the opening 80 is also less than the diameter of end 72 of tension member 64.

It can be appreciated that tension member 64 can be 20 advanced through opening 74 until shaft 70 is disposed therein. Shaft 70 can be then slid transversely through groove 76. Tension member 64 can then be advanced further through opening 73 until end portion 72 enters opening 78 and seats against base 80.

25 Figure 26 shows the view of heart 14 shown in Figure 25. Needle 60 has been removed from heart 14. Tension

member 64 has been advanced into chamber 10 and anchor 68 connected thereto is engaging the heart wall. Leader 66 has been advanced through yet another anchor 68 disposed on the opposite side of heart 14.

5 Figure 27 is a view of heart 14 of Figure 26. Two tension member 64 have been advanced through chamber 10. Each tension member has been seated in respective opening 78 against respective bases 80 to form a splint in a configuration such as that shown in Figure 9.

10 It can be appreciated that each of the other tension member splints configurations can be placed on the heart in a similar manner. It can also be appreciated that anchors 68 could initially be held against the heart and needle 60 advanced through anchors 68 and chamber 10
15 prior to extending leader 66 through the needle.

Figure 28 is a perspective view of a tension member 164 in accordance with the present invention. Tension member 164 is similar to tension member 64 described above in that it has an elongate, generally cylindrical shaft 170 and generally cylindrical ends 172. A lumen, however, extends longitudinally through tension member 164 along axis A.

Figure 29 is a perspective view of yet another embodiment of the tension member 264. Tension member 264, is similar to tension member 164, and includes an elongate cylindrical shaft 270 and cylindrical ends 272.

Lumens 282, however, extend through ends 272 aligned along axis B.

Figure 30 is a vertical, cross-sectional view of left ventricle 10 of heart 14. Anchors 68 have been 5 placed on opposite sides of heart 14. A needle 160 extends through the lumen of tension member 164, left ventricle 10 and openings 73 in anchors 68. It can be appreciated that tension member 64 can be advanced through anchors 68 and left ventricle 10 and be seated 10 within openings 78 as described above with respect to tension member 64.

Figure 31 is a vertical, cross-sectional view of left ventricle 10 of heart 14. A needle 60 has been advanced through the wall of left ventricle 10 and a 15 guidewire 162 has been advanced through needle 60.

Figure 32 is the same view of heart 14 as shown in Figure 32. Needle 60, however, has been removed from heart 14 while guidewire 162 remains in position. Anchors 68 have been placed on guidewire 162, on opposite 20 sides of left ventricle 10. Tension member 264 has been threaded onto guidewire 162 through lumens 282. It can be appreciated that as discussed above with respect to tension member 164 above, tension member 264 can be.. advanced through left ventricle 10 such that ends 272 of 25 tension member 264 seat in respective openings 78 against base 80.

Figure 33 is a vertical, cross-sectional view of left ventricle 10 of heart 14. In Figure 34, flexible tension member 364 has been connected to a needle 360. Needle 360 is shown being advanced into left ventricle 10 5 through a ventricle wall.

Figure 34 is the same view of heart 14 as shown in Figure 33 except that tension member 364 has been advanced entirely through left ventricle 10 and anchors 68. Knots 384 have been tied at the ends of tension 10 member 364 to prevent the ends of tension member 364 from passing through opening 73 of anchors 68.

It can be appreciated that the methods described above to advance the tension members through the ventricles can be repeated to advance the desired number 15 of tension members through the ventricle for a particular configuration. The length of the tension members can be determined based upon the size and condition of the patient's heart. It should also be noted that although the left ventricle has been referred to here for 20 illustrative purposes, that the apparatus and methods of this invention can also be used to splint multiple chambers of a patient's heart as well as the right ventricle or either atrium.

Figure 35 is a vertical cross-section of left 25 ventricle 10 of heart 14. Disposed about heart 14 is a band 716. Band 716 is shown as being sized relative to

the heart such that the heart's radius or cross-sectional area in a plane parallel to the length of the band is reduced relative to the radius at that location prior to placement of the band on the heart. The length of the 5 heart perpendicular to the band is also increased. The band may be formed from a continuous ribbon of elastomeric material or from other biocompatible materials which are sufficiently strong to provide the desired effect of heart radius reduction and lengthening.

10 Figure 36 is a view of a cylinder or idealized heart chamber 48 which is used to illustrate the reduction of wall stress in a heart chamber as a result of deployment of the splint in accordance with the present invention. The model used herein and the calculations related to 15 this model are intended merely to illustrate the mechanism by which wall stress is reduced in the heart chamber. No effort is made herein to quantify the actual reduction which would be realized in any particular in vivo application.

20 Figure 37 is a view of the idealized heart chamber 48 of Figure 36 wherein the chamber has been splinted along its length L such that a "figure eight" cross-section has been formed along the length thereof. It should be noted that the perimeter of the circular 25 transverse cross-section of the chamber in Figure 36 is equal to the perimeter of the figure eight transverse

cross-section of Figure 37. For purposes of this model, opposite lobes of the figure in cross-section are assumed to be mirror images.

Figure 38 shows various parameters of the Figure 1 cross-section of the splinted idealized heart chamber of Figure 37. Where l is the length of the splint between opposite walls of the chamber, R_2 is the radius of each lobe, θ is the angle between the two radii of one lobe which extends to opposite ends of the portion of the splint within chamber 48 and h is the height of the triangle formed by the two radii and the portion of the splint within the chamber 48 (R_1 is the radius of the cylinder of Figure 36). These various parameters are related as follows:

$$15 \quad h = R_2 \cos (\theta/2)$$

$$l = 2 R_2 \sin (\theta/2)$$

$$R_2 = R_1 \pi / (2\pi - \theta)$$

From these relationships, the area of the figure eight cross-section can be calculated by:

$$20 \quad A_2 = 2\pi(R_2)^2 (1-\theta/2\pi) + hl$$

Where chamber 48 is unsplinted as shown in Figure 36 A₁, the original cross-sectional area of the cylinder is equal to A_2 where $\theta = 180^\circ$, $h = 0$ and $l = 2R_2$. Volume equals A_2 times length L and circumferential wall tension equals pressure within the chamber times R_2 times the length L of the chamber.

Thus, for example, with an original cylindrical radius of four centimeters and a pressure within the chamber of 140 mm of mercury, the wall tension T in the walls of the cylinder is 104.4 newtons. When a 3.84 cm 5 splint is placed as shown in Figures 37 and 38 such that $\ell = 3.84$ cm, the wall tension T is 77.33 newtons.

Figures 39 and 40 show a hypothetical distribution of wall tension T and pressure P for the figure eight cross-section. As θ goes from 180° to 0° , tension T_s in 10 the splint goes from 0 to a $2T$ load where the chamber walls carry a T load.

In yet another example, assuming that the chamber length L is a constant 10 cm, the original radius R_1 is 4 cm, at a 140 mmHg the tension in the walls is 74.7 N. 15 If a 4.5 cm splint is placed such that $\ell = 4.5$ cm, the wall tension will then be 52.8 N.

It will be understood that this disclosure, in many respects, is only illustrative. Changes may be made in details, particularly in matters of shape, size, 20 material, and arrangement of parts without exceeding the scope of the invention. Accordingly, the scope of the invention is as defined in the language of the appended claims.

What is claimed is:

1. A heart wall tension reduction apparatus, comprising:

a first tension member having two oppositely disposed ends; and

first and second anchor members, the first anchor member being disposed proximate one end of the tension member and the second anchor member being disposed proximate the opposite end of the tension member.

2. The heart wall tension reduction apparatus in accordance with claim 1, wherein the first anchor member comprises a first pad having a length and a width, and the second anchor member comprises a second pad having a length and a width, and the first and second pad each have two lengthwise ends.

3. The heart wall tension reduction apparatus in accordance with claim 2, wherein the length of the pads is greater than the width of the respective pad.

4. A heart wall tension reduction apparatus in accordance with claim 2, further comprising a second tension member having two oppositely disposed ends; and one lengthwise end of the first pad is disposed proximate one end of the first tension member, and the opposite

lengthwise end of the first pad is disposed proximate one end of the second tension member, and one lengthwise end of the second pad is disposed proximate the end of the first tension member opposite the first pad, and the opposite lengthwise of the second pad is disposed proximate the end of the second tension member opposite the first pad.

5. The heart wall tension reduction apparatus in accordance with claim 4, wherein the length of the first pad is greater than the width of the respective pads.

6. The heart wall tension reduction apparatus in accordance with claim 1, further comprising a third anchor member, and a second tension member having two oppositely disposed ends; wherein the third anchor member is disposed proximate one end of the second tension member and the first anchor member is disposed proximate the opposite end of the second tension member.

7. The heart wall tension reduction apparatus in accordance with claim 6, wherein the first anchor member comprises a first pad having a length and width, and the second anchor member comprises a second pad having a length and a width, and the first and second pads each have two lengthwise ends.

8. The heart wall tension reduction apparatus in accordance with claim 7, wherein the length of the pads is greater than the width of the respective pad.

9. The heart wall tension reduction apparatus, comprising:

an elongate compression member having first and second ends;

first and second elongate lever members, the first lever member extending from the first end of the compression member, and the second lever member extending from the second end of the compression member; and

a tension member extending between the first and second lever members.

10. A heart wall tension reduction apparatus in accordance with claim 9, wherein each of the two lever members have two ends, one end of each of the two lever members is disposed proximate the compression member, the other end of each of the two lever members is disposed remotely from the compression member, and the tension member is disposed closer to the ends of the two lever members disposed proximate the compression member than the ends disposed remotely therefrom.

11. A method of disposing a heart wall tension reduction apparatus on a human heart having a plurality of chambers, comprising the steps of:

providing a heart wall tension reduction apparatus including an elongate compression member having first and second ends; first and second elongate lever members, the first lever member extending from the first end of the compression member, and the second lever member extending from the second end of the compression member; a tension member extending between the first and second lever members; and

extending the tension member through at least one chamber of the human heart.

12. A method in accordance with claim 11, further comprising the step of disposing the compression member external to the heart.

13. The method in accordance with claim 11, further comprising the step of disposing at least a portion of the compression member within the heart.

14. A heart wall tension reduction apparatus, comprising:

a rigid elongate frame member having a first end and a second end;

a first cantilever member disposed at the first end of the frame member; and

a second cantilever member disposed at the second end of the frame member.

15. A heart wall tension reduction apparatus in accordance with claim 14, wherein each cantilever member includes at least one atraumatic pad disposed thereon.

16. A heart wall tension reduction apparatus in accordance with claim 14, further comprising a plurality of cantilever members disposed at the first and second ends of the frame member.

17. The method of placing a heart wall tension reduction apparatus on a human heart having a plurality of chambers, comprising the steps of:

extending a hollow needle through at least one chamber of the heart such that each end of the needle is external to the chamber;

providing a tension member having first and second ends, and a flexible leader connected to the first end of the tension member;

connecting the second end of the tension member to a first atraumatic pad;

advancing the leader through the needle from one end of the needle to the other;

further advancing the leader until the first atraumatic pad engages the heart and the first end of the tension member is external to the at least one chamber; and

connecting the first end of the tension member to a second atraumatic pad such that the second atraumatic pad engages the heart.

18. The method in accordance with claim 17, wherein the length of the tension member is such that the at least one chamber of the heart is compressed between the first and second atraumatic pads.

19. The method of placing a heart wall tension reduction apparatus on a heart having a plurality of chambers, comprising the steps of:

extending a guide member through at least one chamber of the heart such that each end of the guide member is external to the chamber;

providing a tension member having at least one lumen extending therethrough;

extending a portion of the guide member through the lumen;

advancing the tension member on the guide member such that a first end of the tension member is disposed to one side of and external to the at least one chamber, and a second end of the tension member is disposed to an opposite side of and external to the at least one chamber; and

connecting a first atraumatic pad to the first end and a second atraumatic pad to the second end of the tension member.

20. The method in accordance with claim 19, wherein the length of the tension member is such that the at least one chamber of the heart is compressed between the first and second atraumatic pads.

21. A method in accordance with claim 19, wherein the guide member includes a needle.

22. The method in accordance with claim 19, wherein the guide member includes a guidewire.

23. The method of placing a heart wall tension reduction apparatus on a heart having a plurality of chamber comprising the steps of:

extending a needle having a flexible tension member releasably connected thereto through at least one chamber

of the heart such that opposite ends of the tension member are external to the chamber and exposed on opposite sides thereof;

removing the needle from the tension member; and connecting a first atraumatic pad to one end of the tension member and a second atraumatic pad to the opposite end of the tension member.

24. A method in accordance with claim 23, wherein the length of the tension member is such that the at least one chamber of the heart is compressed between the first and second atraumatic pads.

Fig.1

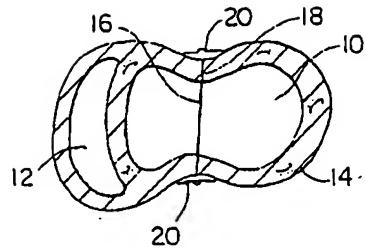


Fig.2

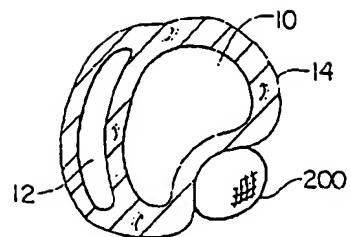


Fig.3

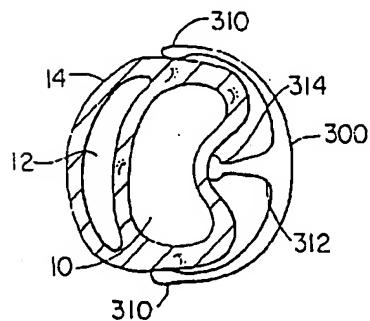


Fig.4

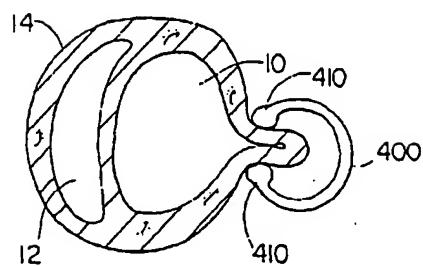


Fig.5

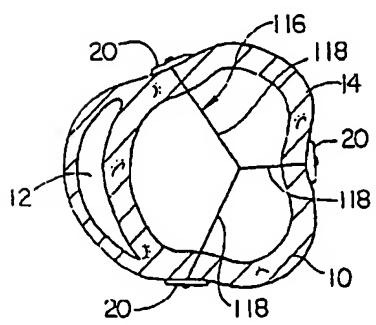
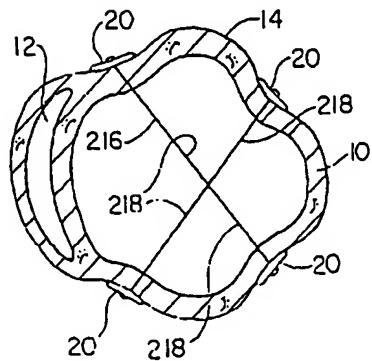


Fig.6



2/8

Fig.8

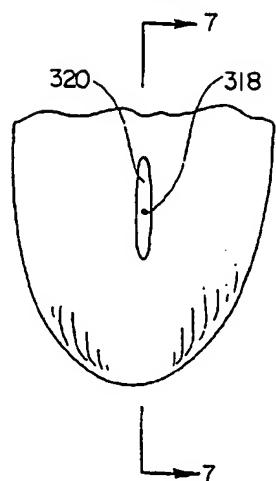


Fig. 7

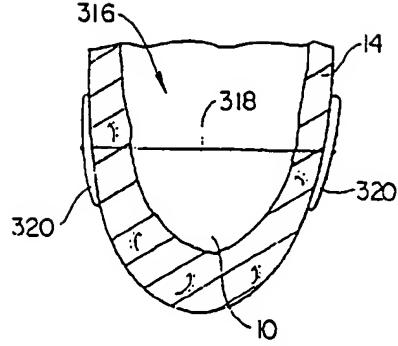


Fig. 9

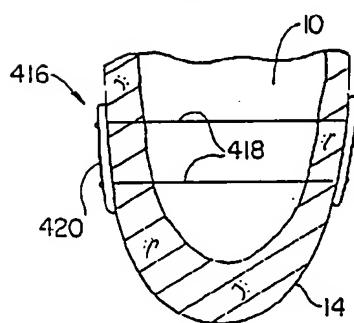


Fig. 10

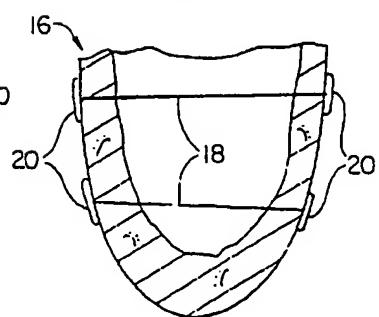


Fig. 11

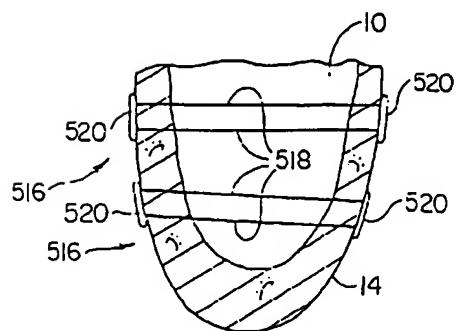
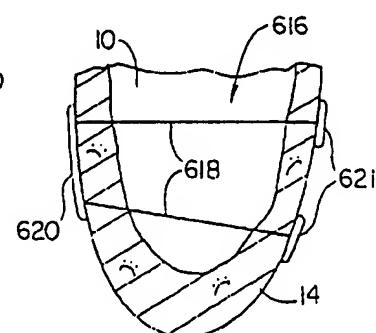


Fig. 12



3/8

Fig.13

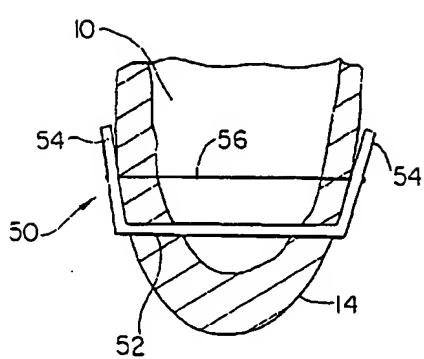


Fig.14

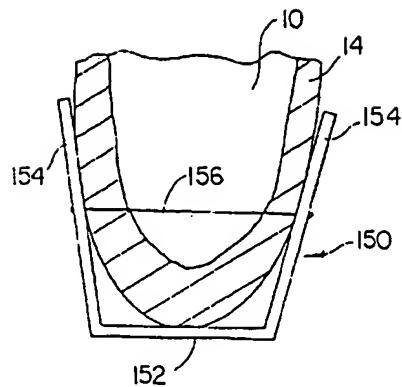


Fig.15

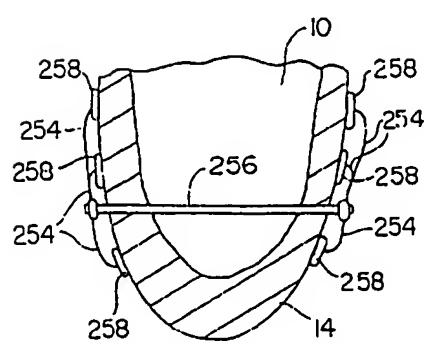
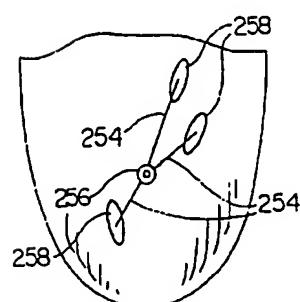


Fig.16



4/8

Fig. 17

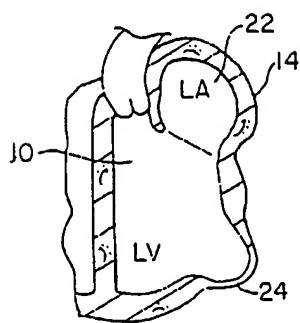


Fig. 18

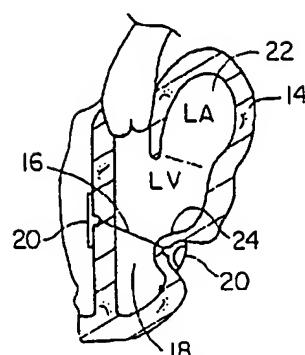


Fig. 19

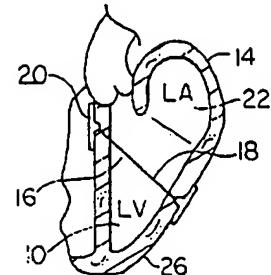


Fig. 22

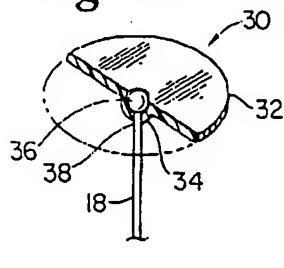


Fig. 23

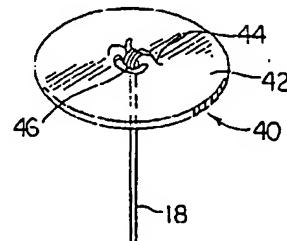


Fig. 20

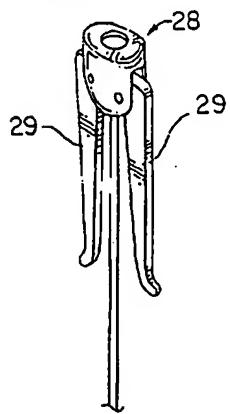


Fig. 21

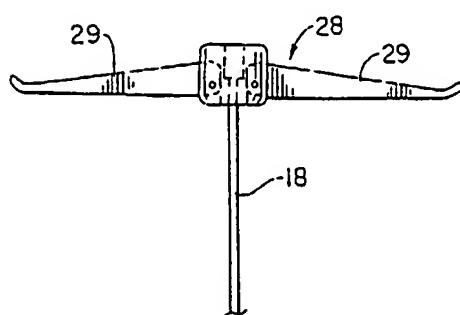
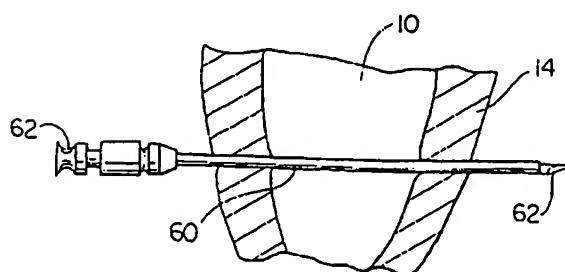
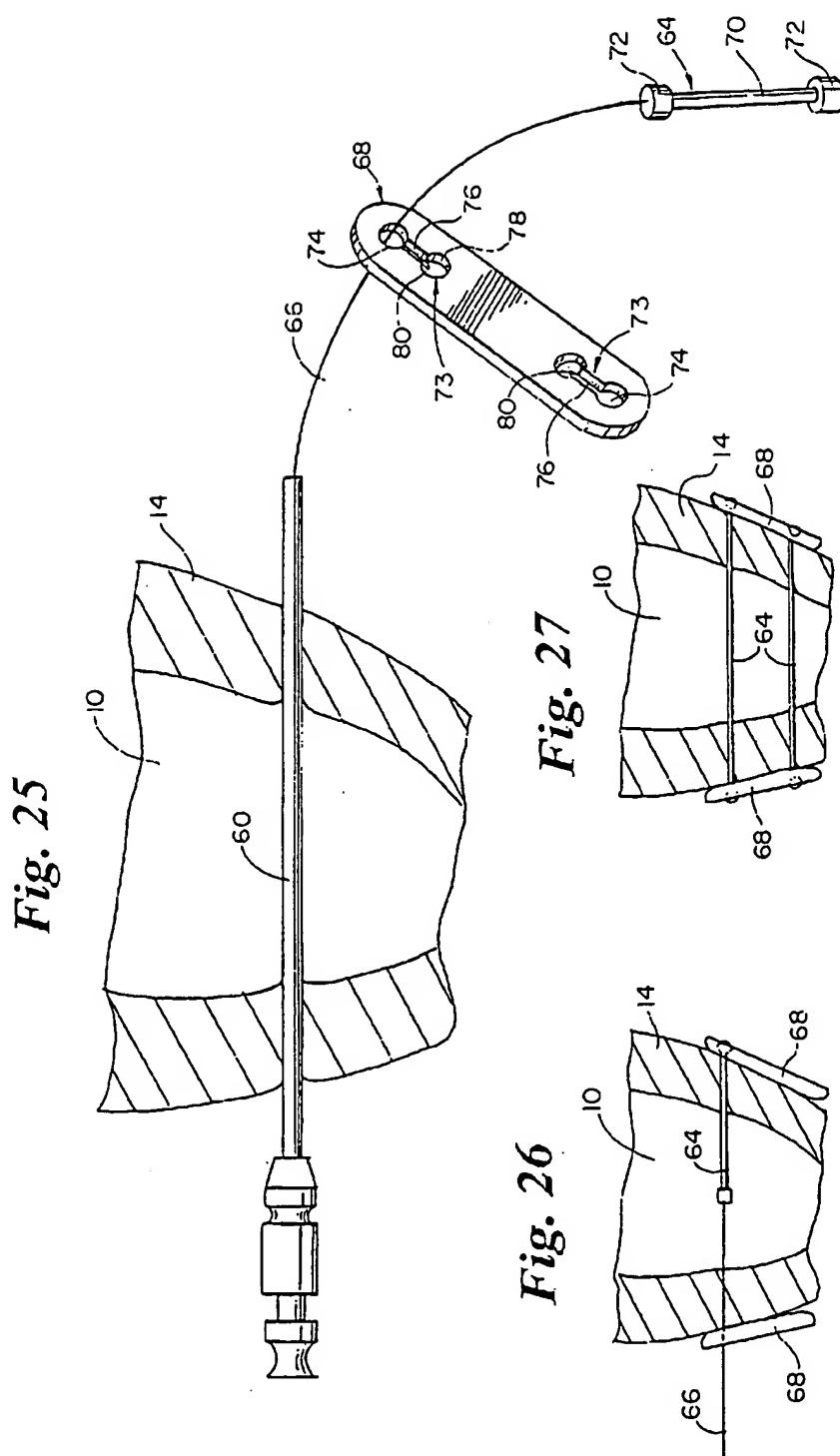


Fig. 24





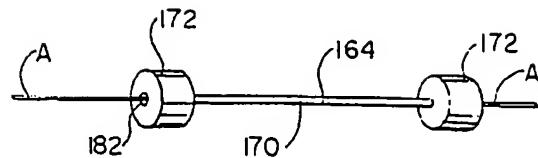
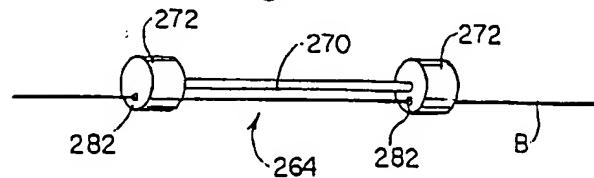
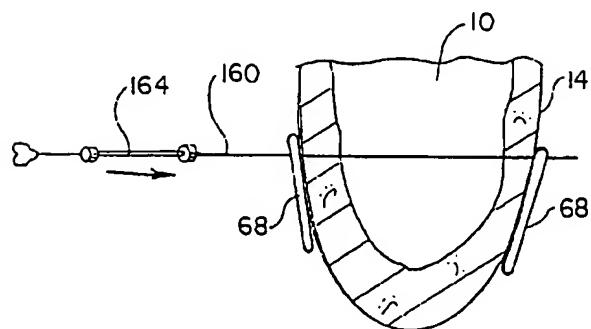
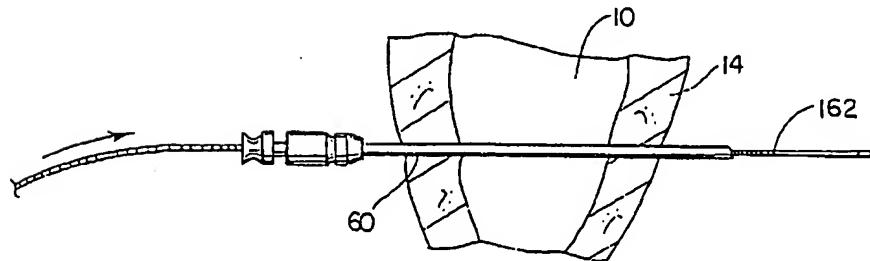
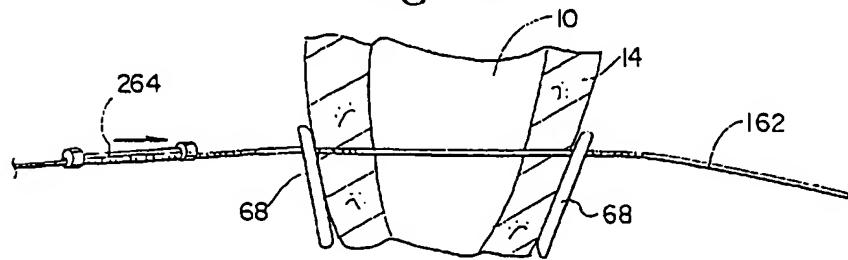
6/8
Fig. 28*Fig. 29**Fig. 30**Fig. 31**Fig. 32*

Fig. 33

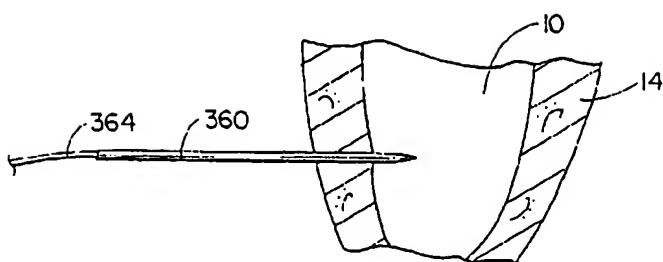


Fig. 34

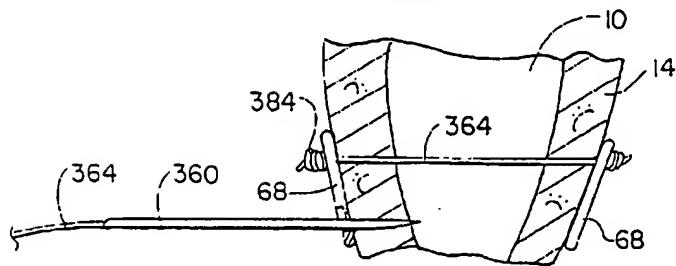


Fig. 35

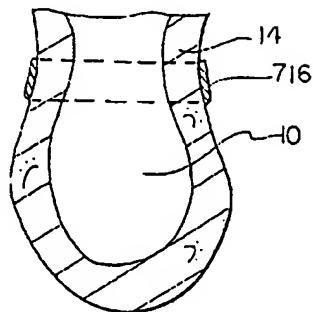


Fig. 36

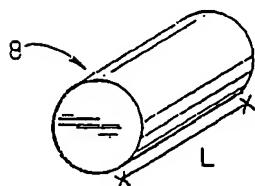
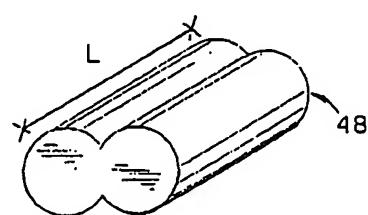


Fig. 37



8/8

Fig. 38

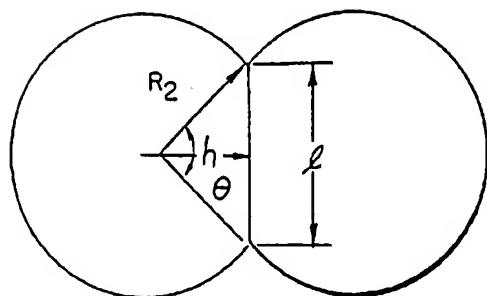


Fig. 39

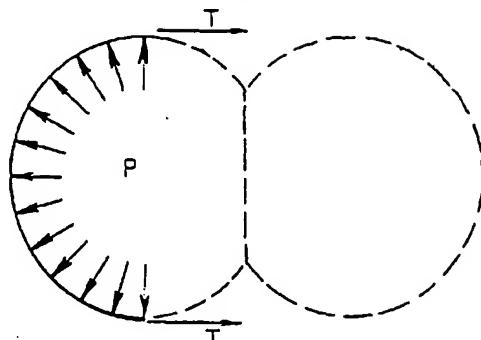
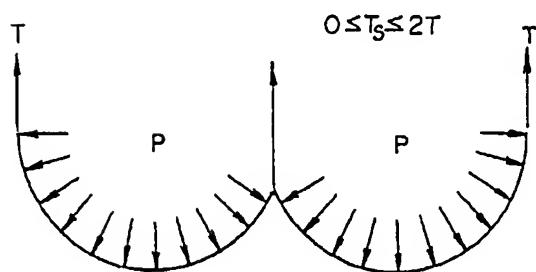


Fig. 40



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/24116

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/12
US CL :600/016

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/897; 600/016-018, 037; 601/011, 153; 623/003, 011

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,192,314 A (DASKALAKIS) 09 March 1993, entire document.	1
X,P	US 5,702,343 A (ALFERNES) 30 December 1997, entire document.	1

 Further documents are listed in the continuation of Box C. See patent family annex.

Special categories of cited documents:		
A document defining the general state of the art which is not considered to be of particular relevance	*T*	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
B earlier document published on or after the international filing date	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
C document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
D document referring to an oral disclosure, use, exhibition or other means	*Z*	document member of the same patent family
E document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

16 FEBRUARY 1998

Date of mailing of the international search report

09 MAR 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JEFFREY R. JASTRZAB

Telephone No. (703) 308-2097